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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Michael Horstmann et al.
Serial No.: 10/581,867
Filed: June 5, 2006 / Conf. No. 3928
Title: INHALER FOR BASIC PHARMACEUTICAL AGENTS AND
METHOD FOR THE PRODUCTION THEREOF
Examiner: _____ / Art Unit: _____
Attorney File: RO4244US (#90568)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

LETTER

Sir:

Submitted herewith for inclusion in the record for the referenced patent application is a copy of an English translation of the "International Preliminary Report on Patentability". Our client advises that the date of completion of the report is February 27, 2006.

Respectfully submitted,

By: _____

DPH/SM/ck
Enc.

D. Peter Hochberg
Reg. No. 24,603

D. Peter Hochberg Co., L.P.A.
1940 E. 6th Street - 6TH Floor
Cleveland, Ohio 44114
Phone: (216) 771-3800
Fax: (216) 771-3804
e-mail: DPHDOCKET@aol.com

Certificate of Mailing

I hereby certify that this document, and anything indicated as being attached or enclosed, is being deposited with the United States Postal Service as First Class mail in an envelope addressed: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450, on the date noted below.

Christine Kotran: Christine Kotran

Date: January 4, 2007

TRANSLATION

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference LTS 2003/008 PCT	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/EP2004/012947	International filing date (day/month/year) 16.11.2004	Priority date (day/month/year) 05.12.2003
International Patent Classification (IPC) or national classification and IPC A24F47/00, A61 M15/06		
Applicant LTS LOHMANN THERAPIE-SYSTEME AG		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.	
2. This REPORT consists of a total of <u>7</u> sheets, including this cover sheet.	
3. This report is also accompanied by ANNEXES, comprising:	
a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>5</u> sheets, as follows:	
<input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).	
<input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.	
b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).	
4. This report contains indications relating to the following items:	
<input checked="" type="checkbox"/> Box No. I	Basis of the report
<input type="checkbox"/> Box No. II	Priority
<input checked="" type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/> Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/> Box No. VI	Certain documents cited
<input checked="" type="checkbox"/> Box No. VII	Certain defects in the international application
<input type="checkbox"/> Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/012947

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____ which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-18 _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ the claims:
- nos. _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* 1-23 _____ received by this Authority on 16.08.2005 with letter
- nos.* _____ received by this Authority on of 11.08.2005
- ☒ the drawings:
- sheets 1/5-5/5 _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (specify): _____
- ☐ any table(s) related to sequence listing (specify): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (specify): _____
- ☐ any table(s) related to sequence listing (specify): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/012947

Box No. III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 7, 8, 22, 23

because:

☐ the said international application, or the said claims Nos. _____
relate to the following subject matter which does not require an international preliminary examination (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 7, 8
are so unclear that no meaningful opinion could be formed (*specify*):

See Supplemental Box

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 22, 23

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/012947

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-6, 9-21	YES
	Claims		NO
Inventive step (IS)	Claims	1-6, 9-21	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-6, 9-21	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Reference is made to the following documents:

D1: US 4765348
D2: US 4800903
D3: US 5746227
D4: GB 1017032.

Document D1 discloses the features of the preamble of claim 1 (see figure 3; column 2, lines 31-35) and the additional features of the following dependent claims:

- claim 2: see column 2, lines 48-50
- claim 5: see column 2, line 39
- claim 6: see column 2, line 33
- claim 10, 11: see column 2, lines 55-59
- claim 12: see column 2, line 54.

Document D3 discloses the features of the preamble of claim 1 (see claim 30; column 4, lines 55-57) and the additional features of the following dependent claims:

- claims 3, 4: see column 5, line 8
- claim 9: see column 2, line 9.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/012947

Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

Document D3 discloses the features of the preamble of claim 1 (see column 2, lines 17-20).

The features of the characterizing part of claim 1 are not known from or suggested by the available prior art.

Claims 2-6 and 9-17 are dependent on claim 1 and are therefore likewise considered novel and inventive. The method claims 18-21 relate to a device according to claim 1 and are therefore likewise considered novel and inventive.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

The features of the claims are not followed by reference signs placed between parentheses (PCT Rule 6.2(b)).

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box III.1

Claims 7 and 8 do not meet the requirements of PCT Article 6 because the subject matter for which protection is sought is not clearly defined. These claims attempt to define the subject matter in terms of the results to be achieved, but in so doing merely state the problem to be solved, without specifying the technical features necessary to achieve the result.

Claims 22 and 23 concern a method for the treatment of the human or animal body by therapy (PCT Rule 39.1(iv)), that is to say smoking cessation and the administration of the medical drugs Selegilin and mecamylamine (see page 2, lines 21 to 27).